IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION

No. 1:19-md-2875-RBK
Hon. Robert Kugler
Hon. Joel Schneider

API MANUFACTURER DEFENDANTS' FACT SHEET

In accordance with Case Management Order No. __, within 60 days of being served with a substantially completed Plaintiff Fact Sheet ("PFS"), the API manufacturer Defendants ("API Manufacturer Defendants") must complete and serve this Defendant Fact Sheet ("DFS") on each Plaintiff's counsel identified in the PFS and on Plaintiffs' Co-Lead Counsel. To the extent necessary to provide complete responses, the Defendants shall confer and share information prior to the deadline for serving their responses. The Defendants will not be required to serve a DFS until Plaintiff supplies a substantially completed and verified PFS, which must provide all of the information requested in section one of the PFS, including copies of prescription and/or pharmacy records demonstrating use of a Valsartan-containing drug, and for personal injury Plaintiffs including medical records and/or a certification under oath demonstrating that he or she has been diagnosed with cancer.

Each served API Manufacturer Defendant must complete the section(s) of this DFS that correspond with that Defendant's role(s) in the supply chain for the Affected Drugs (defined below). Each response must provide the substantive information requested to the extent the information is reasonably accessible to the responding Defendant.

In filling out this form, Defendants must respond on the basis of information and/or documents that are reasonably available to the Defendant and use the following definitions:

"AFFECTED DRUGS": The Valsartan-containing drugs identified in the PFS, to the extent lot, batch or other identifiers allow confirmation of drug source. If an API Manufacturer cannot conclude that they provided the API for a Valsartan-containing drug, they shall so state herein.

"AFFECTED API": The Valsartan API for any Affected Drug(s).

"DOCUMENTS": "Documents" as used in this request is coextensive with the meaning of the terms "documents," "electronically stored information" and "tangible things" as used in the Federal Rules of Civil Procedure, and shall have the broadest possible meaning and interpretation ascribed to those terms. To the extent "Documents" refers to electronically stored information, the scope shall be interpreted as consistent with the scope of communications contemplated by the Electronic Discovery Protocol (Dkt. 127) agreed to by the parties.

"YOU," "YOUR," or "YOURS": Means the responding Defendant.

I. CASE INFORMATION

This DFS pertains to the following case: _____
Case Name and Docket Number

Date that this DFS was completed: _____

Defendant completing this DFS: _____

II. API MANUFACTURERS

A. Identify whether you manufactured the API found in any Affected Drug(s) and, if so, which Affected Drug(s). Identify which Affected Drug(s) and Affected API(s) (i) were actually or potentially contaminated with any nitrosamine or other carcinogenic substance, or (ii) were recalled by you or any other person in relation to potential nitrosamine or other carcinogenic contamination.

B. For each Affected API listed in response to Question II.A, provide the date the API was manufactured, the place of manufacture (by facility, city, state/province, and country), the date of expiry for the Affected API, and the date when the manufacturing process was completed.

C. For each Affected API listed in response to Question II.A, identify all entities that supplied any ingredient, solvent, or other material used in the manufacture of these APIs, and state which material, solvent, or ingredient was supplied by each, and which date those supplies or materials were used to manufacture the Affected API.

D. If known, for each Affected Drug listed in response to Question II.A, identify all ingredients and raw materials used in the manufacture of the Affected Drug other than the Affected API.

E. Identify the entity or entities to which you sold or distributed each Affected API listed in response to Question II.A, the date on which each sale or distribution occurred, the price, and all documentation provided to the purchaser or distributor in connection with that sale or distribution.

F. Identify any testing done on each batch or lot of Affected API listed in response to Question II.A that you were provided or conducted (1) to identify impurities, (2) to identify nitrosamines, and/or (3) that identified any impurity or artifact, including but not limited to a nitrosamine, (4) state the full result of that testing; and (5) your affirmative decisions, if any, to sequester or sell the API tested as a result of the foregoing.

G. State whether you supplied each test result identified in response to Question II.F to the FDA or to any other entity or person (e.g., your actual or prospective customers), and, if so, identify the test result and provide the recipient of the test result, date of communication, and content of the communication.

H. Provide the date(s) on which you sent any recall notice to any Defendants or pharmacies identified in the PFS, or any of your actual or prospective customers of the Affected API listed in response to Question II.A, and attach the recall notice(s).

I. Identify all Affected API or Affected Drugs that you have recalled or otherwise identified as actually or potentially contaminated with any nitrosamine or other carcinogenic substance.

J. Were any Affected API or Affected Drugs sold, distributed, labeled, or manufactured in whole or in part by you ever returned to your possession as a result of a recall letter, or finding or suspicion of contamination?

Yes____ No____

If yes, please identify and produce:

1. The date you regained possession or control of the drugs;

2. The current location of the drugs; and

3. If any, the date and result of any nitrosamine-related testing done on the returned drugs.

If no, but you have knowledge of the location of the drugs, provide the location:

K. Have you communicated directly with Plaintiff at any time?

Yes____ No____

If yes, produce all documents evidencing or relating to that contact including video or audio recording of such contacts.

L. For personal injury cases, if you contend that any person, entity, medical condition, food, medication, or product, other than the Defendants and the Affected Drug(s) is a cause of the plaintiff's injuries ("Alternate Cause"):

1. Identify the Alternate Cause with specificity.

2. Set forth the date(s) and mechanism of alternate causation.

III. DOCUMENTS

To the extent you have not already done so, please produce a copy of all documents and things that fall into the categories listed below. These include documents in the possession of any of your present and former employees and agents, including information provided to your attorneys:

1. Any document created before the filing of this lawsuit which relates to or refers to Plaintiff other than documents received or produced in discovery in this matter.

2. Subject to limitations set forth in this fact sheet concerning timeframes and categories of relevant information, any document sent to or received from any of Plaintiff's Prescribing Health Care Providers identified in the PFS and/or Primary Treating Physician identified in the PFS.

3. Communications including "Dear Doctor," "Dear Health Care Provider," "Dear Colleague" letters, or PIRs sent to or received from any of Plaintiff's Prescribing Health Care Providers identified in the PFS and/or Primary Treating Physician identified in the PFS, regarding Valsartan.

4. Subject to limitations set forth in this fact sheet concerning timeframes and categories of relevant information, any and all documents reflecting any contacts or communications between you and any of Plaintiff's Prescribing Health Care Providers identified in the PFS and/or Primary Treating Physician identified in the PFS, regarding Valsartan.

5. Any and all documents which purport to describe, analyze, investigate, track, and/or report the prescribing practices of any of Plaintiff's Prescribing Healthcare Providers identified in the PFS and/or Primary Treating Physician identified in the PFS relating to Valsartan subject to the approval and/or agreement of the owner of the prescribing data to release the data, which approval and/or agreement Defendant will request.

6. Any and all documentation of the information provided in Section II above.

VERIFICATION

I am Legal Counsel for _____, a Defendant named in this litigation. I am authorized by this Defendant to execute this certification on each corporation's

behalf. I hereby certify that the information provided in the accompanying Response to Defendants' Fact Sheet is not within my personal knowledge, but the facts state therein have been assembled by authorized employees and counsel, upon which I relied. I hereby certify, in my authorized capacity, that the responses to the aforementioned Defendants' Fact Sheet are true and complete to the best of my knowledge on information and belief.

Date:_____ _____
Signature

Name:_____

Employer: _____

Title: _____